SEP 5 2002

K020647

510(k) Summary
Dideco S.p.A. *electa*
(per 21 CFR 807.92)

1. SPONSOR/APPLICANT

Contact: Mr. Luigi Vecchi
Dideco, S.p.A.
via Statale 12 Nord, 86
I-41037 Mirandola (MO)
Italy
Telephone: 011 39 535 298 11
Facsimile: 011 39 535 252 29

2. DEVICE NAME

Proprietary Name: *electa*
Common/Usual Name: Autotransfusion Device
Classification Names: Autotransfusion Apparatus

3. PREDICATE DEVICES

- Dideco ABMS K982650
- Cobe Brat II K991986

4. INTENDED USE

The Dideco *electa* is indicated for intraoperative and postoperative recovery of blood, washing of the processed blood, and pre-operative sequestration (with indirect and direct patient connection). Typical clinical applications of autotransfusion include the following surgical specialties: Cardiovascular, Orthopedics, Thoracic, Transplant Surgery, Emergency (Trauma), Neurosurgery, Obstetrics and Gynecology, and Urology.

5. DEVICE DESCRIPTION

The Dideco *electa* consists of hardware and disposables. It is the next generation of the Dideco autotransfusion device family. The main elements of the hardware include the centrifuge, blood pump, automatic clamps, control and monitoring sensors, and a user interface (display panel and keyboard). The modifications to the disposables are the addition of a bar code to the bowl and the addition of a tubing cassette to simplify disposables installation.

6. BASIS FOR DETERMINATION OF EQUIVALENCE

Dideco makes the claim of substantial equivalence to cited predicates based on intended use, Indications for Use, technological characteristics, and operational characteristics. A side-by-side comparison of the Dideco *electa* with cited predicates is provided in Table I-1 below.

Table I-1. Side-by-Side Comparison of the *electa* and Predicate Devices

Characteristic	*electa*	Dideco ABMS K982650	COBE BRAT II with CRIT-LINE K991986
Intended Use			
Pre-operative Sequestration	Yes	Yes	Yes
Intraoperative recovery of shed blood	Yes	Yes	Yes
Postoperative collection of shed blood	Yes	Yes	Yes
PPP	Yes	Yes	Yes
PRP	Yes	Yes	Yes
Bag processing for PRP	Yes	Yes	Yes
Direct Draw processing for PRP	Yes	Yes	Yes
Typical Clinical Applications			
Cardiovascular Surgery	Yes	Yes	Yes
Orthopedic Surgery	Yes	Yes	Not specified
Thoracic Surgery	Yes	Yes	Not specified
Transplant Surgery	Yes	Yes	Not specified
Emergency (Trauma)	Yes	Yes	Yes
Neurosurgery	Yes	Yes	Not specified
Obstetrics and Gynecologic Surgery	Yes	Yes	Not specified
Urologic Surgery	Yes	Yes	Not specified

Table I-1. Side-by-Side Comparison of the *electa* and Predicate Devices (Continued)

Characteristic	*electa*	Dideco ABMS K982650	COBE BRAT II with CRIT-LINE K991986
Operating Modes			
Automatic	Yes	Yes	Yes
Semi-automatic	Yes	Yes	Yes
Manual	Yes	Yes	Yes
Pre-programmed and reprogrammable	Yes	Yes	Yes
Processing Phases			
Prime (Fill)	Yes	Yes	Yes
Wash	Yes	Yes	Yes
Empty	Yes	Yes	Yes
Return	Yes	Yes	Yes
Concentrate	Yes	Yes	Yes
Disposables			
Bowl sizes	55, 125, 175, and 225	55, 125, 175, and 225	135, 250
Sterile, single use, and disposable	X	X	X
Features			
Cardiotomy weighing system	Yes	No	No
Hematocrit sensor	Yes	No	Yes
Air bubble sensor	Yes	Yes	Yes
Free hemoglobin sensor	Yes	No	No
Pressure occlusion sensor	Yes	No	No
Blood loss sensor	Yes	No	No
Buffy coat sensor	Yes	Yes	Yes
Bar code reader	Yes	No	No
Level sensor	Yes	No	No
Vacuum pump	Yes	No	Yes
Smart card	Yes	No	RS232 Option
Printer	Yes	No	Yes
Continuous operation capability	Yes	No	Up to three cycles
Better quality wash option	Yes	Yes	No
Emergency wash option	Yes	Yes	No

Table I-1. Side-by-Side Comparison of the *electa* and Predicate Devices (Continued)

Characteristic	*electa*	Dideco ABMS K982650	COBE BRAT II with CRIT-LINE K991986
Operating Parameters			
Centrifuge speeds (RPM)	1500-5600	1500-5600	4400
Pump speeds (mL/min)	25-1000	25-1000	25-1300
Blood source for PPP/PRP	Patient or bag	Patient or bag	
PPP collection parameters	50 mL/min 5600 RPM	50 mL/min 5600 RPM	50 mL 4400 RPM
PRP collection parameters	50 mL/min 2400 RPM	50 mL/min 2400 RPM	50 mL 4400 RPM
Vacuum level	0 to 300 mmHg	NA	50 – 300 mmHg

Dideco S.p.A. believes that the *electa* is substantially equivalent to the Dideco ABMS, COBE Brat II, and other currently marketed automated autotransfusion devices, that any differences are minor, and raise no new issues of safety and effectiveness.

7. TESTING

Testing supplied in the 510(k) premarket notification for the Dideco *electa* includes electrical testing, electromagnetic compatibility testing, and performance testing that demonstrate compliance with performance specifications.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 5 2002

Dideco S.p.A. *electa*
Ms. Rosina Robinson
c/o Medical Device Consultants, Inc.
49 Plain Street
North Attleboro, MA 02760

Re: K020647
Dideco *electa*
Regulation Number: 868.5830
Regulation Name: Autotransfusion Apparatus
Regulatory Class: Class II (two)
Product Code: CAC
Dated: June 24, 2002
Received: June 25, 2002

Dear Ms. Robinson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

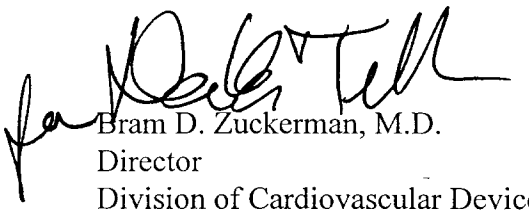
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known):

Device Name: Dideco *electa*

Indications for Use:

The Dideco *electa* is indicated for intraoperative recovery of blood, washing of blood collected in the post-operative period, and pre-operative sequestration (with indirect and direct patient connection). Typical clinical applications of autotransfusion include the following surgical specialties:

- Cardiovascular
- Orthopedics
- Thoracic
- Transplant Surgery
- Emergency (Trauma)
- Neurosurgery
- Obstetrics and gynecology
- Urology

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K020647

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109)